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Atty. Dkt. No. 034827-9103

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Caulfield, et al.

Title: DETERMINATION OF  
TESTOSTERONE BY MASS  
SPECTROMETRY

Appl. No.: 10/726,919

Filing Date: 12/2/2003

Examiner: Unknown

Art Unit: 1645

<p><b>CERTIFICATE OF MAILING</b></p> <p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below.</p> <p>Line Gauthier (Printed Name)</p> <p><i>Line Gauthier</i> (Signature)</p> <p>October 8 2004 (Date of Deposit)</p>
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TRANSMITTAL

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith for filing in the above application are the following:

- 1) Supplemental Information Disclosure Statement (2 pages);
- 2) PTO Form SB/08 (1 sheet);
- 3) Three (3) references; and
- 4) Return Postcard.

Although no fees are believed to be due, the Commissioner is hereby authorized to charge any fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. **50-0872**. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. **50-0872**.

Respectfully submitted,

Date 10/7/04

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By Barry S. Wilson  
Barry S. Wilson  
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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

**RELEVANCE OF EACH DOCUMENT**

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

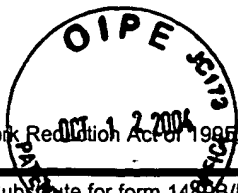
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MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1485B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  Date Submitted: October 7, 2004  (use as many sheets as necessary)				<b>Complete if Known</b>	
				<b>Application Number</b>	10/726,919
				<b>Filing Date</b>	12/2/2003
				<b>First Named Inventor</b>	Michael P. Caulfield
				<b>Group Art Unit</b>	1645
				<b>Examiner Name</b>	Unknown
<b>Sheet</b> 1 <b>of</b> 1				<b>Attorney Docket Number</b>	034827-9103

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>6</sup>
	A1	D. B. Robb et al., "Atmospheric Pressure Photoionization: An Ionization Method for Liquid Chromatography—Mass Spectrometry," <i>Anal. Chem.</i> 72:3653-3659 (2000)		
	A2	B. Starcevic, et al., "Liquid Chromatography—tandem Mass Spectrometry Assay For Human Serum Testosterone And Trideuterated Testosterone," <i>Journal of Chromatographyl B</i> 792:197-204 (2003)		
	A3	T. M. Williams, et al., "Electrospray Collision-induced Dissociation of Testosterone and Testosterone Hydroxy Analogs," <i>Journal of Mass Spectrometry</i> 34:206-216 (1999)		

DLMR260620.1

<b>Examiner Signature</b>		<b>Date Considered</b>	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.